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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,635	08/09/2001	Nanna Kristensen Soni	4305/1H520US1	2913

7590 09/12/2005

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EXAMINER	
FOLEY, SHANON A	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,635	SONI ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S-8D

DETAILED ACTION

Prosecution is reopened upon further consideration of the prior art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 67, 68 and 70-72 are rejected under 35 U.S.C. 102(a) as being anticipated by Beckett (US 6,048,553) as evidenced by Chan (Human Experimental Toxicology. 1996; 15(9): 747-750, abstract only) and Fleming et al. (Contact Dermatitis. 1998; 38 (6) 337).

Claims 67, 68 and 70-72 are rejected under 35 U.S.C. 102(e) as being anticipated by Beckett (US 6,328,997).

Since '553 and '997 have identical disclosures, citations provided are derived from '997 for purposes of simplicity.

The claims are drawn to a vaccine formulation comprising at least one immunogen and an adjuvant, magnesium carbonate hydroxide pentahydrate.

Beckett anticipate teaches preventing and treating clinical signs of influenza by administering a magnesium carbonate solution, see example 7 in column 40, lines 44 to column 41, line 31 and example 10, in column 44, lines 34-58. The magnesium carbonate solution is magnesium carbonate hydroxide pentahydrate administered parenterally, see column 13, lines

16-25 and lines 41-43, column 14, line 62-66, column 16, lines 10-13 and column 18, lines 41-45. Beckett also teach using different adjuvants, buffers and pharmaceutical carriers for administration, see column 18, line 41 to column 19, line 14. Beckett teaches including peppermint oil and/or wintergreen with the composition, see column 18, lines 17-21. Since wintergreen and peppermint oil are allergens, as evidenced by the teachings of Chan and Fleming et al. respectively, it is determined that Beckett anticipate administering magnesium carbonate hydroxide pentahydrate and an allergen. Although Beckett does not identify magnesium carbonate hydroxide pentahydrate as an adjuvant, its co-administration with an allergen (i.e. wintergreen or peppermint) would result in augmentation of an immune response to the allergen. "[A] prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nontheless inherent in it." See *In re Oelrich*, 666 F.2d at 581. Additionally, the courts have determined that "[I]nherency is not necessarily coterminus with the knowledge of those of ordinary skill in the art." See *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). That is, it need not have been appreciated or recognized that the prior art reference inherently discloses the same invention for the reference to be anticipatory. See *Mehl/Biophile Int'l Corp. v. Milgraum* 192 F.3d 1362, 1365 (Fed. Cir. 1999); *Atlas Power Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckett ('553 or '997).

Beckett does not teach the concentration of the cation recited in the claims. However, each set of references teach using the claimed salts in compositions that are parenterally administered, which would necessarily comprise a molar concentration of cation within each composition. In addition, it is conventional practice in the vaccine arts to optimize the amount of components within a composition for individual administrations. Therefore, each concentration within the recited molar range of cations would have been prima facie obvious alternatives to one another to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 69 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckett ('553 or '997) as applied to claims 67, 68 and 70-74 above, and further in view of Vogel et al. ("A Compendium of Vaccine Adjuvants and Excipients" in Vaccine Design: The Subunit and Adjuvant Approach (Chapter 7), M.F. Powell & M.J. Newmann, Eds. (Plenum Press, New York) 1995, pp. 141-228), supplied by applicant in the IDS of paper no. 5.

The claims are drawn to the parenteral vaccine formulation comprising magnesium hydroxide and an additional adjuvant selected from known adjuvants such as Quil A, MPL and PLG.

See the teachings of Beckett above. Although Beckett does not teach or suggest additionally adding a recited adjuvant in the claims, the references teaches that more than one adjuvant may be added to the composition, see columns 18-19.

Vogel et al. provide a brief summary of known adjuvants. These include MF59, MPL, PLGA and Quil A, see pages 183, 186-187, 198-199, and 210, respectively.

One of ordinary skill in the art at the time the invention was made would have been motivated to add conventional adjuvants to the composition of Beckett to ensure boosting the immune response to the antigen. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for combining the adjuvants of Vogel et al. into the composition of Beckett. because Beckett teach that the composition may comprise more than one adjuvant and Vogel et al. review adjuvants well known in the art. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 6:00 AM - 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shanon Foley
Primary Examiner
Art Unit 1648